Rule-Making Cover Sheet

MAPA-1

TO: **Secretary of State**
ATTN: **Administrative Procedure Officer,**
State House Station 101, Augusta, Maine 04333.

2012-66

1. **Agency:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

ACCEPTED FOR FILING
MAR - 6 2012
SECRETARY OF STATE

2. **Agency umbrella and unit number**: 02-392
(2 digit umbrella # and 3 digit unit #)
3. **Title of rule:** Operation of Wholesalers and Manufacturers

4. **Chapter number assigned to the rule:** 16
(must be 3 digits or less)

5. **Date(s)/method(s) of notice:** Newspaper advertisement by Secretary of State, 10-12-11; mailing to interested parties, 09-29-11; posting on OPOR's web site, 09-28-11

6. **Date(s)/place(s) of hearing(s):** 11-03-11, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. **Type:** ☐ new rule ☒ partial amendment(s) of existing rule

☐ suspension of existing rule ☐ repeal of rule ☐ emergency rule

☐ repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. **Name/phone of agency contact person:** Geraldine Betts, Board Administrator, (207) 624-8625

9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**

☐ Provisional adoption (prior to Legislative review) ☐ Final adoption

☐ Emergency adoption of major-substantive rule

10. **Certification Statement:** I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on February 2, 2012.

Signature: _____
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. **Approved as to form and legality by the Attorney General on** 3/1/12
(date)

Signature: _____
(original signature, personally signed by an Assistant Attorney General)

Printed Name: CHRISTOPHER L. MANN

RECEIVED
MAR - 6 2012
OFFICE OF THE SECRETARY OF STATE
AUGUSTA, MAINE

EFFECTIVE DATE: MAR 11 2012

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 16: OPERATION OF ~~WHOLESALE DRUG OUTLETS~~WHOLESALERS AND MANUFACTURERS

Summary: This chapter sets forth operational requirements for wholesale drug distributors, including ~~wholesale drug outlets~~wholesalers and manufacturers.

1. Purpose

The purpose of this chapter is to implement the Federal Prescription Drug Marketing Act of 1987 by providing minimum standards, terms and conditions for the operation of wholesale drug distributors, including manufacturers.

2. Minimum Requirements for the Storage and Handling of Prescription Drugs and the Establishment and Maintenance of Prescription Drug Records

1. Personnel

A wholesale drug distributor shall employ adequate levels of personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

2. Facilities

All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed or displayed shall:

A. Be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

B. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

C. Have a quarantine area for storage of drugs that are outdated, damaged, defective, deteriorated, misbranded or adulterated, or that are in immediate or sealed secondary containers that have been opened;

D. Be maintained in a clean and orderly condition; and

E. Be free from infestation by insects, rodents, birds or vermin of any kind.

3. Security

All facilities used for wholesale drug distribution shall be secure from unauthorized entry:

A. Access from outside the premises shall be kept to a minimum and be well-controlled;

B. The outside perimeter of the premises shall be well-lighted;

C. Entry into areas where prescription drugs are held shall be limited to authorized personnel;

D. All facilities shall be equipped with an alarm system to detect entry after hours; and

E. All facilities shall be equipped with a security system that provides suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

4. Storage

A. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium.

B. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality and purity are not adversely affected.

C. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices and/or logs shall be utilized to document proper storage of prescription drugs.

D. The recordkeeping requirements in Section 2(7) of this chapter shall be followed for all stored drugs.

5. Examination of Materials

A. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

B. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

C. The recordkeeping requirements in Section 2(7) of this chapter shall be followed for all incoming and outgoing prescription drugs.

6. Returned, Damaged and Outdated Prescription Drugs

A. Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

B. Any prescription drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a prescription drug has been returned to the wholesaler cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be quarantined and physically separated from other prescription drugs and shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling as a result of storage or shipping.

D. The recordkeeping requirements in Section 2(7) of this chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs.

7. Recordkeeping

Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

A. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

B. The identity and quantity of the drugs received and distributed or disposed of; and

C. The dates of receipt and distribution or other disposition of the drugs;

D. Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of these rules for a period of 2 years following disposition of the drugs;

E. Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of these rules.

8. Written policies and procedures

Wholesale drug distributors shall establish, maintain and adhere to written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

A. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

B. A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) Any action initiated at the request of the FDA or other federal, state or local law enforcement or other government agency, including the board;

(2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action undertaken to promote public health and safety by replacing existing merchandise with an approved product or new package design.

C. A procedure to ensure that wholesale drug outlets prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency; and

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or

destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

9. Responsible individuals

Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

10. Compliance with Law

A. Wholesale drug distributors shall operate in compliance with 21 USC §353(e), the other federal laws and rules specified in Chapter 29, Section 1 of the board's rules, and other applicable state and local laws and rules.

B. Wholesale drug distributors shall permit the board and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

C. Wholesale drug distributors that deal in controlled substances shall register with the DEA and shall comply with all applicable DEA rules.

11. Salvaging and Reprocessing

Wholesale drug distributors shall be subject to the provisions of any applicable federal, state or local laws or rules that relate to any drug product salvaging or reprocessing, including 21 CFR Parts 207, 210 and 211, Subpart K.

STATUTORY AUTHORITY: 32 M.R.S.A. §§13720, 13721(1), 13722, 13723, 13751(3), 13758

EFFECTIVE DATE:
November 8, 2004 - filing 2004-518